

Appl. No. 09/646,111

Amendment dated: September 16, 2003

Reply to OA of: April 16, 2003

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claims 1-41 (canceled).

42(new). A crystallisation process for lactose[✓] or lactose[✓] monohydrate comprising:

- a) dissolving the substance to be crystallised in an aqueous solution of a Carbomer[✓];
- b) applying a means for adjusting the viscosity of the aqueous solution of a Carbomer until a gel with an apparent viscosity in the range 25 to 90 Pa.s at a shear rate of $1s^{-1}$ is reached;
- c) allowing crystal growth;
- d) applying a means for adjusting the viscosity of the aqueous solution of a Carbomer until a fluid with an apparent viscosity less than 25 Pa.s at a shear rate of $1s^{-1}$ is reached; and
- e) harvesting the crystals.

43(new). A crystallisation process as claimed in claim 42, wherein the means for adjusting the viscosity of the medium¹¹² is temperature change, ultrasound, thixotropy, electro-rheology, mechanical shear, chemical additive, or pH change.

44(new). A crystallisation process as claimed in claim 43, wherein the means for adjusting the viscosity of the medium¹¹² is pH change.

45(new). A crystallisation process as claimed in claim 42, wherein the crystals are harvested by means of collection by filtration.

Appl. No. 09/646,111

Amendment dated: September 16, 2003

Reply to OA of: April 16, 2003

46(new). A crystallisation process as claimed in claim 42, wherein the process comprises:

- a) dissolving the ^{11~}substance to be crystallised in an aqueous solution of a Carbomer wherein the viscosity of the medium is pH-dependent;
- b) adjusting the pH of the aqueous solution of a Carbomer until a gel with an apparent viscosity in the range 25 to 90 Pa.s at a shear rate of 1s^{-1} is reached;
- c) allowing crystal growth;
- d) adjusting the pH of the aqueous solution of a Carbomer until a fluid with an apparent viscosity less than 25 Pa.s at a shear rate of 1s^{-1} is reached; and
- e) harvesting the crystals.

47(new). Lactose monohydrate crystals obtained according to the process as claimed in claim 42.

48(new). A pharmaceutical formulation for administration by inhalation comprising lactose monohydrate crystals as claimed in claim 47.

49(new). A pharmaceutical formulation for administration by inhalation comprising lactose monohydrate crystals as claimed in claim 47 and/or fluticasone propionate or salmeterol xinafoate crystals.

50(new). A crystallisation process as claimed in claim 42, wherein the substance to be crystallised is lactose monohydrate and the crystallised lactose monohydrate has an elongation ratio of 1.58 ± 0.33 and a size in the range of 63 to 90 μm .

51(new). A lactose monohydrate according to claim 47, having an elongation ratio 1.58 ± 0.33 and a size in the range of 63 to 90 μm .

Appl. No. 09/646,111

Amendment dated: September 16, 2003

Reply to OA of: April 16, 2003

D
cont 52(new). Lactose monohydrate according to claim 47, having an elongation ratio
of from 1.55 -2.20.
